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09/439,311	11/12/1999	IANFONG H. LEE	78.560	1500

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

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10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/439,311	Applicant(s) Ianfong et al
Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Nov 12, 1999

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above, claim(s) 2 and 8-15 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 and 3-6 is/are rejected.

7) Claim(s) 7 is/are objected to.

8) Claims 1-15 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

6) Other: _____

Art Unit: 1645

DETAILED ACTION

Claims 1-15 are pending.

Claims 1, 3-7 are under consideration.

Claims 2, 8-15 stand withdrawn from consideration.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1, 3-7 in Paper No. 4, dated September 25, 2000 is acknowledged. A traversal was not set forth in paper number 4. This is not found persuasive because no arguments were made of record. The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

3. The information disclosure statement filed September 25, 2000 has not considered prior to first action.

Art Unit: 1645

Ans 5b (complaint)

Sequence Compliance

4. Applicant's submission of a new sequence disk, and insertion of SEQ ID Nos into the figures is acknowledged.

Specification

5. The disclosure is objected to because of the following informalities: At page 19, line 21, a blank space is present. Clarification of what is missing is requested.

Ans 5b (complaint)

28) ~~omitted~~

Claim Objections

6. Claim 7 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must depend from another claim in the alternative; claim 7 depends from both claim 4 and claim 5, but not in the alternative. See MPEP § 608.01(n). Accordingly, the claim 7 will not be further treated on the merits.

7. Claims which recite abbreviations without prior definition of the abbreviation in the claims are objected to because of the following informalities: Abbreviations are permitted in the claims upon the a definition of the abbreviation upon its first appearance in the claims. Appropriate correction is required.

Art Unit: 1645

Claim Rejections - 35 U.S.C. § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

JK
9. The claimed polynucleotide sequence of claims 1 and 3 is not isolated and purified; the claimed invention is directed to non-statutory subject matter.

Claim Rejections - 35 U.S.C. § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to polynucleotide sequence encoding a polypeptide that is a portion of flaA. A portion that encodes a FlaA polypeptide would be at least 6 nucleotides in length, to encode a two amino acid containing polypeptide (“poly” meaning more than one, peptide being a sequence of amino acids). What is the functional use would a polynucleotide that encodes a polypeptide of two amino acids have in view of the guidance of Winstanley et al (1997) that

Art Unit: 1645

Very *and* *so* *shows* *highly* *conserved* *amino* *acid* *polypeptides* *over* *a* *number* *of* *bacterial* *species* *and* *genera*

to *NH* *encodes* *(see* *Figure* *2*, *page* *3074*)? *What* *would* *a* *polynucleotide* *of* *6* *nucleic* *acids* *that* *encodes* *such* *a*

conserved *amino* *acid* *sequence* *be* *used* *for* *as* *it* *would* *not* *evidence* *any* *specificity* *in* *a* *method* *of*

detecting *Campylobacter*? *What* *real* *world* *use* *would* *such* *a* *reagent* *have* *if* *it* *were* *not*

specific *for* *Campylobacter*? *Clarification* *of* *what* *portions* *are* *specific* *for* *Campylobacter* *flaA*

polynucleotide *encoding* *polypeptides* *is* *requested*.

Claim *1* *is* *directed* *to* *a* *polynucleotide* *sequence* *that* *encodes* *a* *polypeptide* *that* *is* *a* *portion* *of* *the* *flaA* *gene* *of* *Campylobacter*. *A* *functional* *bacterial* *gene* *encompasses* *much* *more* *than* *a* *protein* *coding* *region* *(see* *Davis* *et* *al.*, *Microbiology*, *page* *267*). *A* *bacterial* *gene* *is* *conventionally* *associated* *with* *positive* *and* *negative* *controlling* *elements* *such* *as* *promoters* *and* *repressors* *in* *a* *concordantly* *regulated* *transcription* *unit* *called* *an* *operon*, *without* *which*, *no* *protein* *is* *expressed*. *In* *light* *of* *the* *claimed* *invention* *being* *directed* *to* *a* *portion* *of* *a* “*flaA* *gene*” *which* *includes* *a* *portion* *of* *the* *coding* *sequence* *for* *the* *polypeptide*, *what* *is* *the* *non*
coding *portion* *of* *the* *claimed* *polynucleotide* *that* *is* *associated* *with* *the* *flaA* *gene* *that* *is* *being* *claimed*?

Claim *1* *recites* *both* “*open*” *and* “*closed*” *language* *through* *the* *recitation* *of* “*encoding*” *with* *respect* *to* *a* *Campylobacter* *gene*, *and* “*consisting* *of*”, *respectively*. *The* *claimed* *polynucleotide* *must* *encode* *at* *least* *a* *polypeptide* *that* *is* *a* *portion* *of* *the* *flA* *gene*, *wherein* *the* *portion* *that* *it* *must* *encode* *is* *a* *polypeptide* *defined* *to* *by* *SEQ* *ID* *NO* *1*, *but* *the* *claimed* *polynucleotide* *is* *not* *so* *limited* *to* *just* *SEQ* *ID* *No* *1* *and* *portions* *of* *SEQ* *ID* *NO* *1*, *but* *may*

Art Unit: 1645

include portions of the flaA gene as well. What are the additional structural components of the polynucleotide being claimed? What other portions of the Campylobacter flaA gene are being claimed? Clarification is requested.

Claim 4 recites the phrase "an expression vector wherein the polypeptide of claim 1 is inserted". Claim 1 is directed to a polynucleotide not a polypeptide. While claim 1 provides antecedent basis for the word "polypeptide", the invention of claim 1 is not a polypeptide. An expression system is a vehicle for the expression of a polynucleotide, and insertion of a polypeptide into an expression vector would not be transcribed or translated into a FlaA polypeptide. The expression system is defined to consist of an expression vector. How do the recited expression system and the expression vector differ from one another? Why are both a system and a vector recited in the claim when they have the same components through the recitation of the word "consisting"? Where is the polypeptide of claim 1 inserted in the expression system of claim 4? Clarification of what is inserted into the expression system is requested.

W/ J. Connelly Claim 5 recites the introductory phrase "selected from the group consisting of", but does not set forth Markush group language for the species recited: A and B and C. The species should be set forth "selected from the group consisting of" A, B and C.

W/ J. Connelly Claim 5 defines the expression system to be a plasmid or viral expression vector. How does the recited expression vector also define an expression system? What regulatory or promoter sequences are present for expression? No specific system or sequence for any type of

Art Unit: 1645

expression regulatory sequences are recited in either claim 4 or claim 5 to define any expression sequences for the claimed plasmid, viral vector or E.coli relative to the polynucleotide of claim 1.

Canceled The expression system is defined with apparent closed language "consisting of claim 4". How does the system of claim 4 differ from the vector of claim 5 is additional components to the system have been added to the vector of claim 4? Clarification of what the "system" comprises is requested.

Canceled Claim 5 is also vague and indefinite for depending from claim 4 for the reasons set forth above for claim 4.

Claim 6 recites a series of abbreviations. What do these abbreviations mean? Are these vectors Trademarks for commercial products? If the recited vectors are Trademarked products that should be defined in general terms. If pMal-c2 and pET are Trademarked products, they should be capitalized wherever it appears and be accompanied by the generic terminology.

Canceled Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Clarification of the meaning of the abbreviations recited in claim 6 is requested. Claim 6 is also vague and indefinite for depending from claims 4 and 5, for the reasons set forth above for claim 4.

Art Unit: 1645

Claim Rejections - 35 U.S.C. § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

*1,16
3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Meinersmann et al (US Pat. 5,837,825).*

The claimed invention is directed to a polynucleotide sequence encoding a polypeptide that is a portion of the flaA gene of *Campylobacter*, wherein the polypeptide is defined to contain all or a portion of SEQ ID No 1.

Meinersmann et al disclose an isolated polynucleotide sequence that encodes a polypeptide, wherein the polypeptide is encoded by truncated portion of *Campylobacter* flaA gene. The portion disclosed is truncated at both the 5' and 3' ends and is a 1.1 kb polynucleotide of *Campylobacter* (see col. 9, lines 1-16, especially lines 12-16).

Art Unit: 1645

The isolated polynucleotide that encodes for a portion of Campylobacter FlaA polypeptide was inserted into a lambda bacteriophage vector (see col. 9, line 14), transferred to a plasmid (see col. 9, line 19) and transformed in an E.coli expression system (see col. 9, line 47).

The reference anticipates the instantly claimed polynucleotide that is directed to a portion of a Campylobacter flaA gene, and an expression system into which the polynucleotide has been inserted.

14. ~~Claim 1 and 3~~ are rejected under 35 U.S.C. 102(e) as being anticipated by Shultz et al (US Pat. 6,270,974; effective filing date of March 13, 1998).

Shultz et al disclose the claimed invention directed to:

a polynucleotide sequence encoding a portion of the flaA gene of Campylobacter, wherein the polynucleotide sequence is a portion of the DNA sequence of SEQ ID No 1 (see Shultz et al sequence number 34; sequence alignment provided).

The disclosed sequence of Shultz et al shares 100% sequence identity over 30 nucleotides of SEQ ID No 1, and encodes the amino acids 97-106 of SEQ ID NO 2.

The reference anticipates the instantly claimed invention.

Art Unit: 1645

15. *Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Alm et al (May 1993).*

Alm et al disclose the claimed invention directed to a polynucleotide sequence encoding a portion of the flaA gene of *Campylobacter*, wherein the polynucleotide sequence is a portion of the DNA coding sequence for flaA obtained from *C. coli* VC167-T2, the same strains used by Applicant to obtain the claimed polynucleotide sequence.

The disclosed polynucleotide of Alm et al would inherently comprise and share 100% sequence identity with a portion of SEQ ID No 1, and encodes a portion of the amino acids SEQ ID NO 2 because Alm et al carried out a restriction endonuclease digestion of the coding sequence of flaA, which resulted in 5 portions of DNA, two of which were 202 bp and 250 bp as shown in Figures 1, 3(lane 9) and 4 (lane 8), which do not include the first 12 nucleotides of the 5' end of the coding sequence and are nucleotides within the first three regions of the flaA open reading frame which is represented by SEQ ID NO 1, less the first 12 nucleotides of region 1.

The two endonuclease fragments were not referred to a portions of SEQ ID NO 1, but would inherently anticipates the instantly claimed invention because they were obtained from the same or equivalent open reading from of the flaA gene coding sequence from the same strain of *Campylobacter coli* used to obtain the claimed portion of flaA designated SEQ ID No 1. The polynucleotide sequences encode a portion of the amino acids SEQ ID NO 2 as well.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious

Art Unit: 1645

difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer. “The Court further held that “this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art”.

16. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Alm et al (March 1993).

Alm et al disclose the claimed invention directed to a polynucleotide sequence encoding a portion of the flaA gene of *Campylobacter*, wherein the polynucleotide sequence is a portion of the DNA coding sequence for flaA, wherein the nucleotide was an oligonucleotide portion of SEQ ID NO 1, specifically nucleotides starting at position 50 of SEQ ID No 1 and ending at position 68 of SEQ ID No1. The disclosed polynucleotide shares 100% sequence identity with a portion of SEQ ID No 1(see page 360, col. 1, paragraph 2, bottom of paragraph, reagent referred to as RAA12), and encodes a portion of the amino acids SEQ ID NO 2.

The reference anticipates the instantly claimed invention as now claimed.

Art Unit: 1645

17. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen et al (1996).

Rasmussen et al disclose the claimed invention directed to a polynucleotide sequence encoding a portion of the flaA gene of *Campylobacter*, wherein the polynucleotide sequence is an oligonucleotide portion of SEQ ID NO 1, specifically nucleotides starting at position 428 of SEQ ID No 1 up to position 455 of SEQ ID No1 (see page 363, col. 2, paragraph 2, CA1).

The disclosed polynucleotide of Rasmussen et al shares 100% sequence identity with a portion of SEQ ID No 1, and encodes a portion of the amino acids SEQ ID NO 2. The reference anticipates the instantly claimed invention as now claimed.

Conclusion

18. This is a non-final action.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20. Guerry et al (US Pat. 5,494,795) is cited to show polynucleotide portions of the flaA gene of *Campylobacter*.

21. Kanra, G et al (1997) is cited to show the a method of treating Guillain-Barre syndrome with antibodies.

Art Unit: 1645

22. Khawaja et al (1992) is cited to show lambda gt11 expression library of *Campylobacter jejuni* and analysis of the *flaA* gene (see figure 5, and material and methods).
23. Khoury et al (1995) is cited to show *C. jejuni* *flaA* polynucleotide fragment (780 base pairs) cloned into an expression vector expression system.
24. Meinersmann et al (US Pat. 5,837,825 and 5,888,810) are cited to show a cloned 1.1 kb fragment of *flaA* expressed in an expression vector which was *E.coli* (see col. 9, lines 12-16 and col. 10, lines 1-40, especially lines 36-40 of col. 9.)
25. Nuijten et al (1990) is cited to show a 0.85 kb *flaA* probe and the amino acid sequence of *FlaA* of *C. jejuni* and *C.coli*. (See Figure 5, and Figure 1, page 17799, box with broken line).
26. Nuijten et al (1991) is cited to show *flaA* probe regions of *C. jejuni* (See Figure 1).
27. Ritter et al (US Pat. 5,854,007, col. 3, lines 10-20) is cited to show a method of stimulating antibodies to *Campylobacter jejuni* that bind to GM2 and GM1 monosialogangliosides.
28. Wilson et al (US Pat. 6,355,435) is cited to show guidance and teaching for utilization of *flaA* nucleotide sequence for the determination of *C. jejuni* in a sample (see col. 3, line 38 and col. 4, line 50).
29. Yao et al (1994) is cited to show expression systems that contain isolated *Campylobacter jejuni* *flaA* gene fragments.
- 30.

Art Unit: 1645

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
June 25, 2002

ljs
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